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EXAMINER

AULAKH, CHARANJIT

ART UNIT

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1625

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

1. According to paper filed on April 14, 2008, the applicants have amended claims 23-35 and furthermore, have added new claims 36 and 37.
2. Claims 23-37 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on April 14, 2008 have been fully considered but they are not persuasive regarding obviousness rejection. The applicants have amended claims to overcome indefiniteness rejections. In regard to obviousness rejection, the applicants argue on page 8, second paragraph that the amount of acetic acid used was different in the instant process ( 668 to 1001 mol as compared to the process of Lin ( 197 mol ). However, Lin's reference does not mention this amount at all. It is not clear where the applicants find this amount in Lin's reference. Similarly, Lin's reference is silent about the time of oxidation. The applicant's argue that Wood's reference uses much longer period. However, Wood's reference does not teach oxidation of 7-ethyl-1,2,6,7-tetrahydrocamptothecin and therefore, is irrelevant. Lin clearly demonstrates the beneficial effect of oxidation of 7-alkyl-1,2,6,7-tetrahydrocamptothecin with iodobenzenediacetate in acetic acid/water in order to get 7-alkyl-10-hydroxycamptothecin in high yield ( see col. 3, lines 30-35 ). The declaration filed by the applicants is also irrelevant at this stage. The priority date of the Lin's reference is May 12, 2003 whereas the effective filing date of the instant application is 16 Dec. 2003 and therefore, Lin's reference does qualify as a prior art reference. On the other hand, once all the issues are resolved and an interference is declared with Lin's patented claims (

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claims 2-12 ), only then this declaration will be needed. Also, the applicants need to clarify regarding the structure of 7-ethyl-1,2,6,7-tetrahydrocamptothecin since according to Lin's reference, 7-ethyl-1,2,6,7-tetrahydrocamptothecin ( formula II in column 2, lines 40-48 ) has a double bond present between C6 and C7 whereas it is absent in the instant compounds of formula (IV).

### ***Conclusion***

4. Rejection of claims 23-37 under 35 U.S.C. 103(a) over Lin's reference is maintained for the reasons of record.

### **NEW GROUNDS OF REJECTION**

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 23, the amount of acetic used is listed as 1130 mol per 1 mol of 7-ethyl-1,2,6,7-tetrahydrocamptothecin. This introduces new matter since according to the specification, this amount can only be 668 to 1001 mol ( see page 4, line 10 ). Similarly, in claim 36, the amount of iodobenzenediacetate

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used is listed as 1.9 mol. However, according to the specification, this amount can only be ) 0.99 to 1.85 mol ( see page 4, line 13 ). This also introduces new matter.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Charanjit S. Aulakh/  
Primary Examiner, Art Unit 1625